

# A CASE SERIES OF DISCORDANT LABORATORY RESULTS WITH RAPID HIV TESTING



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### ISSUES/BACKGROUND:

- The New Jersey Department of Health and Senior Services Division of HIV/AIDS Services (NJDHSS DHAS) introduced rapid HIV testing to improve the proportion of high risk persons testing for HIV and to increase the proportion of people who learn their test result.
- Recently, the U.S. Food and Drug Administration (FDA) approved the first CLIA 'waived', rapid (fingerstick) HIV point-of-care test for use in the United States (OraQuick® Rapid HIV-1 Antibody test, OraSure Technologies, Inc., Bethlehem, PA).
- The purpose of this abstract is to describe a case series of patients with discordant results.

### METHODS:

- Staff at publicly funded counseling and testing sites received counseling and, rapid testing training, completed competency testing and passed proficiency testing prior to offering rapid HIV testing.
- All rapid testing sites were licensed by NJDHSS.
- All rapid testing was completed using OraQuick ® (Orasure Technologies, Inc. Bethlehem, PA) with confirmatory testing via Western blot.

### DISCORDANT RESULTS

DEFINITION: A reactive OraQuick® rapid HIV test followed by a negative or indeterminate Western blot (WB) or immunofluorescent assay (IFA) result.

#### DISCORDANT RESULTS

TWO TYPES OF DISCORDANTS

- **TYPE I**
  - Positive Oraquick ®, NEGATIVE Western Blot
    - *No bands present*
    - Client is considered HIV negative and not likely to be in an HIV window.
- **TYPE II**
  - Positive Oraquick ®, INDETERMINATE Western Blot
    - Some bands not meeting the criteria to be declared positive are present
    - Possibility the client is in the process of seroconverting.

#### STANDARDIZED FOLLOW-UP TESTING:

- Testing for the following medical conditions:
  - Hepatitis A serologies (IgG and IgM)
  - Hepatitis B serologies (HBsAg, anti-HBc, anti-HBs).
  - Epstein Barr virus serologies
  - Rheumatoid factor
- PCR Testing for HIV

### CENTRALIZED HANDLING OF DISCORDANT PROTOCOL

- The protocol for discordant results includes a repeat HIV by Oraquick 4-6 weeks after the initial positive Oraquick result, independent confirmation of the original negative Western blot, collection of additional serum for hepatitis A (HAV), hepatitis B (HBV), hepatitis C (HCV), HIV by standard enzyme immunoassay, Epstein-Barr virus (EBV), and Rheumatoid factor (RF); and collection of additional plasma for ultrasensitive, quantitative RNA determination of HIV. Demographic data were collected using the standard Centers for Disease Control and Prevention counseling and testing form.
- The initial reaction to requests to permit discordant follow-up led to a decision to centralize training and oversight and to employ a standardized, centralized discordant protocol.



### FOLLOW-UP

- Two patients refused to permit follow-up citing a stable, monogamous relationship with a partner who tested negative. Another declined follow-up after confirming a negative EIA status with an ID specialist.
- Two patients returned for follow-up testing.
  - Both tested HIV negative by traditional enzyme immunoassay and both were repeat Oraquick HIV positive upon re-examination 4-6 weeks later.
- One patient completing the discordant protocol was:
  - Repeatedly positive by Oraquick ® and negative by enzyme immunoassay and ultrasensitive RNA analysis.
  - This patient was hepatitis A virus polyvalent antibody positive
  - Had no indications of acute hepatitis A, B or C infection.
  - Rheumatoid factor was within the reference range.
- There was evidence of a distant EBV infection with IgG antibodies to EB nuclear antigen, but no detectable IgM antibodies to viral capsid antigen, or IgG antibodies to early D antigen.
- Further testing by the manufacturer indicated that the specimen was "reacting to material on the device used to bind peptides at the test line and also with the HIV-1."

### RESULTS

- Rapid testing started at one publicly funded counseling and testing site in New Jersey on November 1, 2003. Through December 31, 2004, 48 sites were conducting rapid testing with 10,601 tests completed. Five (0.05%) of these patients met the definition of a discordant case.

### SUMMARY:

- The first two discordants in NJ caused us to reorganize our approach to provide additional training and to centralize the handling of the discordant protocol including wherever possible a direct encounter between laboratory professionals and the affected client.
- To date, all discordants in NJ have been Type I discordants
- The discordant rate in NJ is .05%. This may be attributable to a centralized Quality Assurance program which requires rigorous adherence to laboratory procedures.

Number	First Discordant	Follow-up	Risk Factors	Site	Repeat Oraquick	Western Blot	Repeat Oraquick	Western Blot	Discordant Type	Recent Immigrant	Gender	Race or Ethnicity	Age	Pregnant	Multiparous	HIV PCR	Rheum. Factor	Hep A	Hep B	Hep C	EBV ab to Viral Capsid Ag (IgM)	EBV ab to Nuclear Ag (IgG)	EBV ab to Early (D) Ag	HEP Interp	EBV Interp
One	3/22/2004	No	MSM,MSF	RWJ	Yes +	Neg	Yes +	Refused	Type I	No	Male	White	31	NA	NA	Neg (Anecdotal)									
Two	6/14/2004	No	Heterosexual Pregnant Refused Follow-up Delivered a Healthy baby 1/27/05	PCHC	Yes +	Neg	Yes +	Neg	Type I	Central America	Female	Hispanic	20	Yes	No	No			HBsAg-						
Three	5/28/2004	Yes	Heterosexual	JSMC	Yes +	Neg	Yes +	Neg	Type I	No	Male	Hispanic	34	NA	NA	No									
Four	8/31/2004	Yes	Married - Heterosexual 3 unit Blood Transfusion 3 yrs ago	PCHC	Yes +	Neg	Yes +	Neg	Type I	Central America	Female	Hispanic	34	Yes	Yes - 3	Neg	Normal	Poly +, IgM -	HBsAg - HBcAb - HBsAb -	NEG	NEG	2.79 IU	NEG	No Acute Hepatitis	No Acute EBV infect
Five	12/21/2004	Yes	Sex w HIV + male	NCHC	Yes +	Neg	Yes +	Neg	Type I	No	Female	Black	43	No	Yes - 13	Neg		Poly -	HBsAg - HBcAb - HBsAb -				No Acute Hepatitis		